

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Certificate of Compliance

Catalog Number: 431510

Lot Number: 10114001

Product Description: 1L Erlenmeyer Flask w/Aseptic Connector: 2 Port, 1/8" Diptube, 0.2um Vent, 1/8" C-Flex w/Male LL

Component Materials:

- Flask - Virgin Polycarbonate, meets USP, Class VI requirements for plastic containers and closures.
- Cap - Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and closures. Heavy metal free (meets CONEG requirements) color concentrate.
- Tubing - C-flex thermoplastic elastomer, meets USP, Class VI requirements for Biological Test for Plastics.
- Filter - 50mm filter with 0.2 µm pore PVDF membrane, meets USP Biological Reactivity Test, In Vivo <88>
- Diptube - Polypropylene, meets USP, Class VI
- Male Luer Lock and Cap - Polypropylene, meets USP, Class VI

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (TIR 33) Sterilization of Healthcare Products-Requirements for validation and routine control-Radiation sterilization.
Sterility Assurance Level: SAL 10-6

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Performance Testing:

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure:

Visual Attributes
Packaging

Results:

Pass
Pass

Expiration Statement:

This product has an expiration date of 3 years from the date of manufacture for the attributes contained within this certificate.

Revision Date:

06-12-14



Wendy Loitsch
Quality Manager

Rev No: 3